REMARKS

Claims 1-6 and 9 are pending, claims 7, 8, and 10-11 have been canceled. Claims 1 and 4 have been amended. No new matter has been added by way of these amendments. Support for the amendments can be found in the original claims and throughout the specification. Reconsideration of the pending claims is respectfully requested.

Restriction

Applicants acknowledge the Restriction Requirement and thank the Examiner for including claims 6 and 9 with the elected invention of Group I.

Information Disclosure Statement

Applicants respectfully disagree with the Examiner's refusal to consider the International Search Report because it is allegedly no a published document. The document was published by the World Intellectual Property Organization and as such was made publicly available. Moreover, 37 C.F.R. 1.98(a)(1) provides that an Information Disclosure Statement disclose:

> "A list of all patents, publications, applications, or other information submitted for consideration by the Office. U.S. patents and U.S. patent application publications must be listed in a section separately from citations of other documents."

The Examiner lacks the authority to prevent an applicant from disclosing and having considered a document which it deems relevant.

Regarding the additional references not considered, Applicants have prepared a supplemental Information Disclosure Statement that contains the titles of the non-patent references as required by the rules. Consideration of all the references is respectfully requested.

The Pending Claims are Definite

The pending claims were rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. Specifically, the preamble of the claim recited a method of treatment while the body of

the claim recited a method of preventing. Claim 1 has been amended to rectify this situation, thus obviating this rejection.

The Pending Claims are Supported by an Enabling Disclosure

Claims 1-6 and 9 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking support of an enabling disclosure. "To be enabling, the specification of a patent must teach those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation' ... Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). "'The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.'" *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)).

The present disclosure provides ample support to one of ordinary skill in the regarding how to make and use the present invention. Specifically, those of ordinary skill in the art could readily determine the quantity and frequency of administration of a p38 MAPK inhibitor necessary to treat or reduce symptoms associated with the onset of Type I diabetes in a subject in need thereof. The Examiner is directed to the Examples section wherein therapeutic application of the disclosed technology is discussed. In view of this guidance, Applicants submit that the presently claimed invention is fully supported by an enabling disclosure. As such, the present rejection should be withdrawn.

The Pending Claims are Non-Obvious

Claims 1-6 and 9 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Mavunkel, et al. (U.S. Patent No. 6,589,954) in view of Faustman (U.S. Pub. No. 2002/0123472).

The Examiner bears the burden of establishing a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993). Only if this burden is met does the burden of coming forward with rebuttal argument or evidence shift to the applicant. *Id.* at 1532. When the references cited by the examiner fail to establish a *prima facie* case of obviousness, the rejection is improper and will be overturned. *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). To establish a *prima facie* case of obviousness, the Examiner must, inter alia, show that some suggestion or motivation, either in the references or in the knowledge generally available among those of ordinary skill in the art, to modify the reference. *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). Finding that it would have been "obvious-to-try" to achieve a claimed invention by combining or modifying references, does not meet the Examiner's burden of proof. *See , e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987). Additionally, there must be a reasonable expectation of success found in the prior art. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

Here, the Examiner has, at best, produced an obvious-to-try argument. Specifically, because the Faustman reference teaches a role of p38MAP kinase in inflammation, one of ordinary skill in the art might try the compounds of Mavunkel, et al. to treat diabetes. This tenuous link between the cited references and the claimed subject matter is not sufficient to support a prima facie case of obviousness.

The Examiner has also dismissed the limitations appearing in claims 2, 3, 6, and 9 as allegedly not further limiting the claimed method. This statement is clearly incorrect. The limitations of claims 2 and 3 provide additional information with which one of ordinary skill in the art could use to identify a suitable candidate for treatment by the claimed method. Claims 6 and 9 recite novel and non-obvious results of the claimed method which are not suggested by the cited art.

The use of p38 MAP kinase inhibitors to treat diabetes is novel and non-obvious and thus patentable over the cited art. As such, the present rejection should be withdrawn.

The Pending Claims are Novel

Claims 1-6 and 9 were rejected under 35 U.S.C. § 102(b) as allegedly being by Revesz (U.S. Patent No. 6,300,347).

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference . . . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Revesz does not teaches the use of inhibitors of p38 MAP kinase generically and without any detailed guidance regarding the particular isoforms of the enzyme. The pending claims are directed to the use of compounds with activity toward various specific isoforms. Because the cited reference is silent regarding this feature, it cannot be fairly said to teach each and every limitation of the claimed invention. Therefore, the present rejection should be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 219002032800. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: March 23, 2007

Respectfully submitted,

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